HEALTH CANADA CONDITIONALLY APPROVES BOSULIF – A NEW MEDICATION FOR CHRONIC MYELOGENOUS LEUKEMIA

Approval provides new treatment option for Canadians suffering from rare cancer

KIRKLAND, QC – March 18, 2014 – Health Canada granted conditional approval for BOSULIF (bosutinib) for the treatment of chronic, accelerated, or blast phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML) in adult patients with resistance or intolerance to prior TKI therapy, and for whom subsequent treatment with imatinib, nilotinib and dasatinib is not clinically appropriate (NOC/c).[1] CML is a rare cancer of the blood and bone marrow that is typically diagnosed in adults between the age of 55 and 60.[2] Approximately 5,500 Canadians are currently living with CML, and more than 500 new cases are diagnosed each year.[3,4]

"The approval of BOSULIF represents a new development for Canadians suffering from CML, as some do not respond to, or cannot tolerate, the currently available treatments," says Dr. Jeffrey Lipton, CML Group, Princess Margaret Cancer Centre. "It provides one more tool in the battle against this challenging disease."

Health Canada's issuance of the conditional approval for BOSULIF reflects the promising nature of BOSULIF in patients with this serious disease and the need for further follow-up to verify the clinical benefit. BOSULIF possesses an acceptable safety profile based on the benefit-risk assessment.

CML is characterized by the over-production of abnormal white blood cells, which then crowd out healthy cells.[5] Ninety-five per cent of people with CML have a genetic mutation called the Philadelphia chromosome,[2] which promotes the growth of the leukemia cells.[5]

"The approval of BOSULIF is good news for Canadian patients with CML," says Cheryl-Anne Simoneau, President, The Chronic Myelogenous Leukemia Society of Canada. "It is critical that patients with CML have a range of treatment options available, because there is no one-size-fits-all treatment for this disease."

BOSULIF CLINICAL TRIALS

The safety and effectiveness of bosutinib was evaluated in a single clinical trial with 570 adult patients who had chronic, accelerated or blast phase CML and were treated with BOSULIF. The study included separate cohorts for patients with chronic, accelerated and blast phase disease.[1]

In patients with chronic phase CML, efficacy was determined by the number of patients who experienced a major cytogenetic response (MCyR) within the first 24 weeks of treatment.

The most common side effects observed in those receiving bosutinib (≥20 per cent of patients) were diarrhea, nausea, a low level of platelets in the blood (thrombocytopenia), vomiting, and rash.[1]

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